

Phase I trial: Parexel Code: PXL277433

Submission date 15/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/11/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/11/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr David Steel

Contact details

Parexel Early Phase Clinical Unit (LONDON)
Northwick Park Hospital
Level 7
Watford Road
Harrow
London
United Kingdom
HA1 3UJ
+44 (0)7548098654
david.steel@parexel.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

1007366

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 1007366, Parexel PXL27743

Study information

Scientific Title

Phase I trial: Parexel Code: PXL277433 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 02/08/2023, Brent Research Ethics Committee Health Research Authority (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8128, +44 (0)207 104 8131; brent.rec@hra.nhs.uk), ref: 23/LO/0321; The HRA has approved deferral of publication of trial details.

2. approved 17/08/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 29969/0159/001-0001; The HRA has approved deferral of publication of trial details

Study design

First-in-man safety, pharmacokinetics and pharmacodynamics trial in 88 healthy volunteers

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Interventions

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Primary outcome(s)

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Key secondary outcome(s)

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Completion date

30/08/2024

Eligibility**Key inclusion criteria**

Healthy human volunteers

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

All

Key exclusion criteria

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Date of first enrolment

22/08/2023

Date of final enrolment

30/08/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Parexel International; Parexel Early Phase Clinical Unit

Northwick Park Hospital

Watford Road

Harrow

United Kingdom

HA1 3UJ

Sponsor information

Organisation

Sanofi-Aventis Recherche & Développement

Funder(s)

Funder type

Industry

Funder Name

Sanofi-Aventis Recherche & Développement

Results and Publications

Individual participant data (IPD) sharing plan

Qualified researchers may request access to patient-level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Patient-level data will be anonymized and study documents will be redacted to protect the privacy of trial participants. Further details on

Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at:
<https://vivli.org>

IPD sharing plan summary

Available on request